Reprinted
February 22, 2005

HOUSE BILL No. 1745

DIGEST OF HB 1745 (Updated February 21, 2005 9:09 pm - DI 77)

Citations Affected: IC 10-13; IC 25-26; IC 34-24; IC 35-43; noncode.

Synopsis: Wholesale drug distributor licensure. Expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure. Specifies prohibited acts. Specifies criminal acts related to wholesale drug distribution and legend drugs and devices. Allows the board of pharmacy to establish an electronic pedigree pilot program.

Effective: July 1, 2005.

Budak, Becker, Brown T, Brown C

January 19, 2005, read first time and referred to Committee on Public Health.
January 25, 2005, reported — Do Pass.
February 21, 2005, read second time, amended, ordered engrossed.

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February 22, 2005

First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

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HOUSE BILL No. 1745

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 10-13-3-38.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 38.5. (a) Under federal P.L.92-544 (86 Stat. 1115), the department may use an individual's fingerprints submitted by the individual for the following purposes:

(1) Determining the individual's suitability for employment with the state, or as an employee of a contractor of the state, in a position:

(A) that has a job description that includes contact with, care of, or supervision over a person less than eighteen (18) years of age;

(B) that has a job description that includes contact with, care of, or supervision over an endangered adult (as defined in IC 12-10-3-2), except the individual is not required to meet the standard for harmed or threatened with harm set forth in IC 12-10-3-2(a)(3);

(C) at a state institution managed by the office of the secretary of family and social services or state department of health;

(D) at the Indiana School for the Deaf established by IC 20-16-2-1;

(E) at the Indiana School for the Blind established by IC 20-15-2-1;

(F) at a juvenile detention facility;

(G) with the gaming commission under IC 4-33-3-16;

(H) with the department of financial institutions under IC 28-11-2-3; or

(I) that has a job description that includes access to or supervision over state financial or personnel data, including state warrants, banking codes, or payroll information pertaining to state employees.

(2) Identification in a request related to an application for a teacher's license submitted to the professional standards board established under IC 20-1-1.4.

(3) Use by the Indiana board of pharmacy in determining the individual's suitability for a position or employment with a wholesale drug distributor, as specified in IC 25-26-14-16(b), IC 25-26-14-16.5(b), IC 25-26-14-17.8(c), and IC 25-26-14-20.

An applicant shall submit the fingerprints in an appropriate format or on forms provided for the employment or license application. The department shall charge each applicant the fee established under section 28 of this chapter and by federal authorities to defray the costs associated with a search for and classification of the applicant's fingerprints. The department may forward fingerprints submitted by an applicant to the Federal Bureau of Investigation or any other agency for processing. The state personnel department or the agency to which the applicant is applying for employment or a license may receive the results of all fingerprint investigations.

(b) An applicant who is an employee of the state may not be charged under subsection (a).

(c) Subsection (a)(1) does not apply to an employee of a contractor of the state if the contract involves the construction or repair of a capital project or other public works project of the state.

SECTION 2. IC 25-26-14-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located within or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs ~~within~~ **or devices in** Indiana.

SECTION 3. IC 25-26-14-1.5 IS ADDED TO THE INDIANA

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CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.5. As used in this chapter, "adulterated" refers to a drug or device that:**

(1) consists in whole or in part of a filthy, putrid, or decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions and may have been contaminated or rendered injurious to health;

(3) has been subjected to conditions in the manufacture, processing, packing, or holding of the drug or device that do not conform to current standards of manufacturing to ensure that the drug or device is safe for use and possesses the identity, strength, quality, and purity characteristics that the drug or device is represented to possess;

(4) is contained in a container composed of a poisonous or deleterious substance that may render the drug or device injurious to health;

(5) bears or contains, for purposes of coloring only, a color additive that is unsafe;

(6) is of a different strength, quality, or purity from the official compendium standard for the drug or device; or

(7) does not meet the considerations of the federal Food, Drug, and Cosmetic Act.

SECTION 4. IC 25-26-14-1.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:**

(1) the pedigree of a drug; and

(2) other accompanying documentation for a drug or device; has occurred.

SECTION 5. IC 25-26-14-1.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor, including any affiliated group (as defined in Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member, and a manufacturer if the wholesale drug distributor:**

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(1) has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship;

(2) is listed on the manufacturer's current monthly updated list of authorized distributors; or

(3) has a verifiable account with the manufacturer and a minimal transaction or volume requirement limit of:

(A) five thousand (5,000) units per company in the previous twelve (12) months; or

(B) twelve (12) purchases at the manufacturer's minimum purchasing requirement per invoice in the previous twelve (12) months.

SECTION 6. IC 25-26-14-4.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.1. As used in this chapter, "compendium" refers to:**

(1) the United States Pharmacopoeia;

(2) the Homeopathic Pharmacopoeia of the United States;

(3) the National Formulary;

(4) a drug approved by the federal Food and Drug Administration; or

(5) a supplement to a document specified in subdivision (1), (2), or (3).

SECTION 7. IC 25-26-14-4.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.2. As used in this chapter, "contraband" refers to a drug or device:**

(1) that is counterfeit;

(2) that is stolen;

(3) that is misbranded;

(4) that is obtained by fraud;

(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the drug or device;

(6) for which a required pedigree or documentation does not exist; or

(7) for which a pedigree or documentation in existence:

(A) has been forged, counterfeited, or falsely created; or

(B) contains any altered, false, or misrepresented information.

SECTION 8. IC 25-26-14-4.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.3. As used in this chapter,**

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"counterfeit" refers to a drug or device, or the container, seal, or labeling of a drug or device, that, without authorization, bears the trademark, trade name, or other identifying mark or imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the drug or device.

SECTION 9. IC 25-26-14-4.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.4. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a drug or device from one (1) person to another.**

SECTION 10. IC 25-26-14-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. As used in this chapter, "designated representative" means an individual who:**

(1) is designated by a wholesale drug distributor;

(2) serves as the wholesale drug distributor's responsible individual with the board; and

(3) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

SECTION 11. IC 25-26-14-4.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.6. As used in this chapter, "device" means an instrument, an apparatus, an implement, a machine, a contrivance, an implant, or a similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or State law requires dispensing by or on the order of a physician.".**

SECTION 12. IC 25-26-14-4.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug or device, whether by passage of title or physical movement, or both. The term does not include the following:**

(1) Dispensing or administering a legend drug or device.

(2) Delivering or offering to deliver a legend drug or device by a common carrier in the usual course of business as a common carrier.

(3) The provision of a drug or device sample to a patient by a:

(A) practitioner;

(B) health care professional acting at the direction and

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under the supervision of a practitioner; or

(C) hospital's or other health care entity's pharmacy that received the drug or device sample in accordance with this chapter and other applicable law to administer or dispense and that is acting at the direction of a practitioner;

licensed to prescribe the legend drug or device.

SECTION 13. IC 25-26-14-4.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.8. As used in this chapter, "documentation" means a document in a written or an electronic form that is approved by the board, that records each distribution of a device, from the sale by the manufacturer through acquisition and sale by each wholesale drug distributor, and that includes the following information for each transaction:**

(1) The source of the device, including the name and principal address of the seller.

(2) The:

(A) date of purchase;

(B) sales invoice number;

(C) container size;

(D) number of containers; and

(E) lot number;

of the device.

(3) The:

(A) business name and address of each owner of the device; and

(B) device's shipping information, including the name and address of the facility of each person certifying delivery or receipt of the device.

(4) Information that states that the wholesale drug distributor has acted with due diligence as required under this chapter with respect to another wholesale drug distributor from which the wholesale drug distributor purchased or may have purchased the device.

(5) A certification from the designated representative of the wholesale drug distributor that the information contained in the document is true and accurate under penalty of perjury.

SECTION 14. IC 25-26-14-4.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.9. As used in this chapter, "drug" means the following:**

(1) Articles recognized in an official compendium and

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designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(3) Articles other than food intended to affect the structure or function of the body of humans or animals.

(4) Articles intended for use as a component of an article specified in subdivision (1), (2), or (3).

The term does not include a device or a device component, part, or accessory.

SECTION 15. IC 25-26-14-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. **The term does not include a pharmacy or wholesale drug distributor.**

SECTION 16. IC 25-26-14-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug or device.**

SECTION 17. IC 25-26-14-6.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:**

(1) on a legend drug or device or a legend drug's or device's container or wrapper; or

(2) accompanying a legend drug or device.

SECTION 18. IC 25-26-14-8.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's or device's label:**

(1) is false or misleading;

(2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug or device;

(3) does not show an accurate monograph for the legend drug or device; or

(4) does not comply with any other requirements of the

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federal Food, Drug and Cosmetic Act.

SECTION 19. IC 25-26-14-8.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that records each distribution of a legend drug, from the sale by the manufacturer or, except for drugs on the specified list of susceptible products, from the last authorized distributor of record through acquisition and sale by each wholesale drug distributor, and that includes the following information for each transaction:**

(1) The source of the legend drug, including the name and principal address of the seller.

(2) The:

(A) amount and dosage form and strength;

(B) date of purchase;

(C) sales invoice number;

(D) container size;

(E) number of containers;

(F) lot number; and

(G) proprietary and established name;

of the legend drug.

(3) The:

(A) business name and address of each owner of the legend drug; and

(B) legend drug's shipping information, including the name and address of the facility of each person certifying delivery or receipt of the legend drug.

(4) Information that states that the wholesale drug distributor has acted with due diligence as required under this chapter with respect to another wholesale drug distributor from which the wholesale drug distributor purchased or may have purchased the legend drug.

(5) A certification from the designated representative of the wholesale drug distributor that the information contained in the document is true and accurate under penalty of perjury.

SECTION 20. IC 25-26-14-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, ~~or~~ a corporation, **or another entity, including a governmental entity.**

SECTION 21. IC 25-26-14-9.2 IS ADDED TO THE INDIANA

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CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.2. As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.**

SECTION 22. IC 25-26-14-9.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.3. As used in this chapter, "repackage" means changing the container, wrapper, quantity, or labeling of a legend drug or device to further the distribution of the legend drug or device.**

SECTION 23. IC 25-26-14-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 10.5. As used in this chapter, "specified list of susceptible products" means a specific list of legend drugs or devices established by the board, the board's agent, or a third party approved by the board, as:**

(1) susceptible to adulteration, counterfeiting, or diversion; and

(2) posing the potential for a particular public health risk.

SECTION 24. IC 25-26-14-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 11. As used in this chapter, "wholesale distribution" means ~~distribution of~~ **to distribute** legend drugs **and devices** to persons other than a consumer or patient. The term does not include:

(1) a sale **or transfer** between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug **or device** for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;

(3) the sale of a drug **or device** by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale of a drug **or device** among hospitals or other health care entities that are under common control;

(5) the sale of a drug **or device** for emergency medical reasons, including transfers of legend drugs **or devices** by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue **or device**

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sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;

(6) the sale of a drug **or device** or the dispensing of a drug **or device** pursuant to a prescription;

(7) the distribution of drug **or device** samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug **or device** by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales **or device sales** during any twelve (12) consecutive months; ~~or~~

(10) the sale of a drug **or device** by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;

(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23; or

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

SECTION 25. IC 25-26-14-12 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs **and devices,** including:

(1) manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

(8) independent wholesale drug traders; and

(9) retail and hospital pharmacies that conduct wholesale distributions.

The term does not include a common carrier or person hired solely to transport prescription drugs **or devices.**

SECTION 26. IC 25-26-14-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 14. (a) ~~After September 14, 1992,~~ A person may not engage in wholesale distributions of legend drugs **or devices** without: ~~having~~

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(1) obtaining and maintaining accreditation or certification from an accreditation body approved by the board under subsection (g);

(2) obtaining and maintaining a license ~~from~~ **issued by** the board; and

(3) paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board ~~may~~ **shall** require a separate license for

~~(1)~~ each facility ~~directly or indirectly owned or operated by the same business in Indiana; or~~

~~(2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.~~ **or location where wholesale distribution operations are conducted.**

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs **and devices** when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the department of local government finance on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

(g) The board shall adopt rules under IC 4-22-2 to approve an accreditation body to:

(1) evaluate a wholesale drug distributor's operations to determine compliance with:

(A) professional standards;

(B) this chapter; and

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(C) any other applicable law; and

(2) perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

SECTION 27. IC 25-26-14-14.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a:**

(1) legend drug without a current, accompanying pedigree; or

(2) device without current, accompanying documentation.

SECTION 28. IC 25-26-14-15 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs **and devices.**

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee, including:

(A) if an individual, the name, **address, Social Security number, and date of birth** of the individual;

(B) if a partnership, the name, **address, Social Security number, and date of birth** of each partner, and the name of the partnership **and federal employer identification number;**

(C) if a corporation:

(i) the name, **address, Social Security number, date of birth,** and title of each corporate officer and director;

(ii) the corporate names, ~~and~~ the name of the state of incorporation, **the federal employer identification number, and the name of the parent company, if any; and**

(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;

(D) if a limited liability company, the name of each manager

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and member, the name **and federal identification number** of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, **address, Social Security number, and date of birth** of the sole proprietor and the name **and federal employer identification number** of the business entity.

(6) The name, **address, and telephone number** of the ~~person~~ designated ~~by the licensee as responsible for the operation~~ **representative** of ~~the facilities.~~ **each facility.**

(7) Additional information concerning record keeping required under this chapter.

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

(1) are related to a license held by the wholesale drug distributor;

(2) are authorized under Indiana law; and

(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.

However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:

(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b); or

(2) an appeal of a proceeding described in subdivision (1);

whichever occurs later.

(d) The board shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

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(e) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

~~(b)~~ **(f)** A material change in any information in ~~subsection (a) of~~ this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

SECTION 29. IC 25-26-14-15.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 15.5. (a) A wholesale drug distributor that is an authorized distributor of a manufacturer is not considered to be an authorized distributor of the manufacturer under this chapter unless:**

(1) the manufacturer files the manufacturer's monthly updated list of authorized distributors with the board;

(2) the list is available from the manufacturer upon request or on the Internet; and

(3) the manufacturer notifies the board of any change to the list within ten (10) days after the change.

(b) The board shall make available on the board's Internet web site a manufacturer's list of authorized distributors filed as described in subsection (a).

SECTION 30. IC 25-26-14-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 16. **(a)** In reviewing, **for purposes of licensure or renewal of a license under this chapter,** the qualifications of persons who engage in wholesale distribution of legend drugs ~~within~~ **or devices in** Indiana, the board shall consider the following factors:

(1) A ~~conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.~~ **finding by the board that the applicant has:**

(A) violated a law; or

(B) been disciplined by a regulatory agency for violating a law;

related to drug or device distribution in any state.

(2) A ~~felony~~ **criminal** conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs **or devices**, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug **or device** manufacturing or distribution.

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(5) Suspension or revocation **of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner** by the federal or a state **or local** government ~~of any license held by the applicant~~ for the manufacture or distribution of any drugs **or devices,** including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

(b) In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of a national criminal history background check (as defined in IC 10-13-3-12) for:

(1) the applicant;

(2) all personnel involved in the operations of the wholesale drug distributor;

(3) the most senior individual responsible for facility operations, purchasing, and inventory control, and the individual to whom the senior individual reports;

(4) company officers;

(5) key management personnel;

(6) principals; and

(7) owners with at least a ten percent (10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

The national criminal history background check must be conducted at the applicant's expense and must include all states of residence since the applicant became eighteen (18) years of age.

(c) An applicant shall provide and attest to:

(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or

(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws;

regarding drugs or devices.

SECTION 31. IC 25-26-14-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

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[EFFECTIVE JULY 1, 2005]: **Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.**

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

(1) A set of the designated representative's fingerprints, under procedures specified by the board and according to requirements of the state police department under IC 10-13-3-38.5, with the payment of the amount equal to the costs of a national criminal history background check (as defined in IC 10-13-3-12) of the designated representative to be obtained by the state police department.

(2) The date and place of birth of the designated representative.

(3) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

(4) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of drugs or devices, including details of related events.

(5) A description of any involvement by the designated representative with a business that:

(A) manufactured, administered, prescribed, distributed, or stored drugs or devices; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

(6) A description of any criminal offense of which the designated representative has been convicted, regardless of whether adjudication of guilt was withheld or whether the designated representative pleaded nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board:

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(A) a copy of the notice of appeal; and

(B) a copy of the final written order of disposition.

(7) A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

(8) A list of the name, address, occupation, and date and place of birth of each member of the designated representative's immediate family, including the designated representative's spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings. Information collected under this subdivision is confidential.

(9) Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs or devices.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor facility at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale drug distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs or devices.

SECTION 32. IC 25-26-14-16.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 16.6. (a) A wholesale drug distributor that:**

(1) is licensed under this chapter;

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(2) is located outside Indiana; and

(3) distributes legend drugs or devices in Indiana;

shall designate an agent in Indiana for service of process.

(b) A wholesale drug distributor that does not designate an agent under subsection (a) is considered to have designated the secretary of state to be the wholesale drug distributor's true and lawful attorney, upon whom legal process may be served in an action or a proceeding against the wholesale drug distributor arising from the wholesale drug distributor's wholesale distribution operations.

(c) The board shall mail a copy of any service of process to a wholesale drug distributor by certified mail, return receipt requested, postage prepaid, at the address designated by the wholesale drug distributor on the application for licensure submitted under this chapter.

(d) Service of process on the secretary of state is sufficient in an action or a proceeding against a wholesale drug distributor that is not licensed under this chapter.

SECTION 33. IC 25-26-14-17 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17. As a condition for receiving and retaining ~~any~~ **a** wholesale drug distributor license issued under ~~to~~ this chapter, ~~each~~ **an** applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards **for each facility at which legend drugs or devices are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs or devices are transported, including:**

(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs or devices in the facility are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs or devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected

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counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facility in a clean and orderly condition;

(F) maintenance of the facility in a commercial, nonresidential building; and

(G) freedom of the facility from infestation.

(2) **Security of each facility from unauthorized entry as follows:**

(A) Entry into areas where legend drugs or devices are held is limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

~~(A)~~ **(i)** an after hours central alarm or a comparable entry detection capability;

~~(B)~~ **(ii)** restricted premises access;

~~(C)~~ **(iii)** adequate outside perimeter lighting; ~~and~~

~~(D)~~ **(iv)** safeguards against **theft and diversion, including** employee theft **and theft or diversion facilitated or hidden by tampering with computers or electronic records; and**

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping ~~that~~ **as follows:**

(A) **The system** describes all the wholesale distributor's activities governed by this chapter for the ~~two~~ ~~(2)~~ **three (3)** year period after the disposition of each product and **all records are maintained for at least three (3) years after disposition of the legend drug or device to which the record applies.**

(B) **The system** is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs and devices, including the following:

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that is on the specified list of susceptible products or that

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leaves the normal distribution chain of custody from the manufacturer to a wholesale drug distributor, to a pharmacy, and to the patient or the patient's agent.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug.

(iii) After January 1, 2007, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.

(iv) Dates of receipt and distribution or other disposition of the legend drugs and devices by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection. Records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs and devices or counterfeiting or suspected counterfeiting activities to the board and federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs and devices to the board and federal Food and Drug Administration if diversion is known or suspected.

(4) Written policies and procedures **to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend**

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drugs and devices, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including **the following:**

(A) ~~those~~ **Facility security or operation problems** caused by natural disaster or government emergency.

(B) **Correction of** inventory inaccuracies. ~~or~~

(C) Product shipping and receiving **problems.**

~~(C)~~ **(D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all** outdated ~~product~~ **products and outdated or expired legend drugs and devices, including appropriate documentation and witnessing.**

~~(D)~~ **(E)** Appropriate disposition of returned goods. ~~and~~

~~(E)~~ **(F)** Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

(H) Implementation and maintenance of a continuous quality improvement system.

(I) Recalls and withdrawals of legend drugs and devices due to:

(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;

(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs and devices from the market; or

(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

(J) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(K) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and devices and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.

(L) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs and devices to the board within three (3) business days.

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(M) Conducting for cause authentication and random authentication as required under sections 17.2, 17.3, and 17.8 of this chapter.

(5) **Written policies and procedures and** sufficient inspection procedures for all incoming and outgoing product shipments, **including the following:**

(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs or devices in the container and to determine whether the legend drugs or devices may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs or devices for accuracy and completeness, considering the:

(i) total facts and circumstances surrounding each transaction involving the legend drugs or devices; and

(ii) wholesale drug distributors involved.

(C) Quarantine of a legend drug or device considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:

(i) examination and a determination that the legend drug or device is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or

(ii) the legend drug or device is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug or device was acquired.

(D) Written policies and procedures to ensure that a legend drug or device that was:

(i) ordered in error or in excess of need by the wholesale drug distributor;

(ii) identified within three (3) business days after receipt as ordered in error or in excess of need; and

(iii) maintained such that the legend drug's or device's integrity has not been compromised;

may be returned to the manufacturer or wholesale drug distributor from which the legend drug or device was acquired if the appropriate documentation is completed and necessary notations are made to a required pedigree

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or documentation.

(E) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug or device is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug or device was acquired within three (3) business days.

(F) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug or device is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug or device until the legend drug or device is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug or device was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug or device was acquired within three (3) business days.

(G) Written policies and procedures to ensure that a legend drug or device that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug or device is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug or device was acquired.

(H) Written policies and procedures to ensure that:

(i) a legend drug or device that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug or device is returned.

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(I) Inspection of each outgoing shipment for identity of the legend drugs or devices and to ensure that the legend drugs or devices have not been damaged in storage or held under improper conditions.

(J) Written policies and procedures to ensure that if conditions under which a legend drug or device has been returned to the wholesale drug distributor cast doubt on the legend drug's or device's safety, identity, strength, quality, or purity, the legend drug or device is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug or device was acquired unless examination, testing, or other investigation proves that the legend drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug or device has been returned cast doubt on the legend drug's or device's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug or device has been held, stored, or shipped before or during the legend drug's or device's return and the condition of the legend drug or device and the legend drug's or device's container, carton, or labeling upon receipt of the returned legend drug or device.

(K) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs or devices, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(L) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and federal Food and Drug Administration.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

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(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs or devices.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.

(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs and devices. The technology and equipment meets standards set by the board and is used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs and devices.

(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs and devices due to tampering or adverse storage conditions.

SECTION 34. IC 25-26-14-17.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs or devices from another wholesale drug distributor and has reason to believe that a legend drug or device purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug or device back to the manufacturer.**

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug or device for which a purchasing

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wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information regarding the distribution of the legend drug or device, including the:

(1) date of purchase of the legend drug or device;

(2) lot number of the legend drug or device;

(3) sales invoice number of the legend drug or device; and

(4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug or device.

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug or device, the wholesale drug distributor shall quarantine the legend drug or device and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug or device back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 35. IC 25-26-14-17.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.3. (a) A wholesale drug distributor that purchases legend drugs or devices from another wholesale drug distributor shall, at least annually, conduct a random authentication of a required pedigree or documentation on at least ten percent (10%) of sales units of wholesale distributions of legend drugs or devices purchased from other wholesale drug distributors.**

(b) If a wholesale drug distributor purchases from another wholesale drug distributor a legend drug or device that is on the specified list of susceptible products, the wholesale drug distributor shall, at least quarterly, conduct a random authentication of a required pedigree or documentation on at least ninety percent (90%) of sales units of distributions of legend drugs or devices that are on the specified list of susceptible products and that were purchased from other wholesale drug distributors.

(c) A wholesale drug distributor from whom another wholesale drug distributor purchases legend drugs or devices shall cooperate

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with random authentications of pedigrees or documentation described in this section and provide requested information in a timely manner.

(d) If a wholesale drug distributor conducts a random authentication under this section and is unable to authenticate each distribution of the legend drug or device, the wholesale drug distributor shall quarantine the legend drug or device and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 36. IC 25-26-14-17.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs or devices from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section.**

(b) Before the initial purchase of legend drugs or devices from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs or devices.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the

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unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug or device storage and distribution.

(11) A description of legend drug or device import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs or devices from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs or devices from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that

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purchases legend drugs or devices from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs or devices from an unlicensed wholesale drug distributor has reason to believe that a legend drug or device purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug or device back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug or device for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug or device, including the:

(1) date of purchase of the legend drug or device;

(2) lot number of the legend drug or device;

(3) sales invoice number of the legend drug or device; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug or device.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug or device, the licensed wholesale drug distributor shall quarantine the legend drug or device and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug or device back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs or devices from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees or documentation on at least ten percent (10%) of sales units of distributions of legend drugs or devices that were purchased from unlicensed wholesale drug distributors.

(k) A licensed wholesale drug distributor that has purchased a

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legend drug or device that is on the specified list of susceptible products shall, at least quarterly, conduct random authentications of required pedigrees or documentation on at least ninety percent (90%) of sales units of distributions of legend drugs or devices that:

(1) are on the specified list of susceptible products; and

(2) were purchased from unlicensed wholesale drug distributors.

(l) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs or devices shall cooperate with the random authentications of pedigrees or documentation under this section and provide requested information in a timely manner.

(m) If a wholesale drug distributor conducts a random authentication under subsection (j) or (k) and is unable to authenticate each distribution of the legend drug or device, the wholesale drug distributor shall quarantine the legend drug or device and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 37. IC 25-26-14-17.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by another wholesale drug distributor licensed under this chapter.**

SECTION 38. IC 25-26-14-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 20. **(a)** A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

(b) Before employing a person to be engaged in the operation and handling of legend drugs or devices, a wholesale drug distributor shall request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department for the person.

SECTION 39. IC 25-26-14-21.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:**

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(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug or device that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.

(2) The adulteration, misbranding, or counterfeiting of a legend drug or device.

(3) The receipt of a legend drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug or device for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or device or the commission of another act with respect to a legend drug or device that results in the legend drug or device being misbranded.

(5) Forging, counterfeiting, simulating, or falsely representing a legend drug or device using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(6) The purchase or receipt of a legend drug or device from a person that is not licensed to distribute legend drugs or devices to the purchaser or recipient.

(7) The sale or transfer of a legend drug or device to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug or device to purchase or receive legend drugs or devices from the person selling or transferring the legend drug or device.

(8) Failure to maintain or provide records as required under this chapter.

(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.

(10) The wholesale distribution of a legend drug or device that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(11) Obtaining or attempting to obtain a legend drug or device by fraud, deceit, misrepresentation, or engaging in

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fraud, deceit, or misrepresentation in the distribution of a legend drug or device.

(12) Failure to obtain, authenticate, or provide a required pedigree or documentation.

(13) The receipt of a legend drug or device through wholesale distribution without first receiving a required pedigree or documentation attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug or device that was previously dispensed by a retail pharmacy or distributed by a practitioner.

(15) Failure to report an act prohibited by this section.

(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):

(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.

(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars ($10,000) per violation.

SECTION 40. IC 25-26-14-26 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 26. **(a)** A person ~~that~~ **who knowingly or intentionally** engages in the wholesale distribution of a legend drug **or device** without a license issued under this chapter commits a Class D felony.

(b) A person who engages in the wholesale distribution of a legend drug or device and:

(1) who, with intent to defraud or deceive:

(A) fails to obtain or deliver to another person a complete and accurate required pedigree or documentation concerning a legend drug or device before:

(i) obtaining the legend drug or device from another person; or

(ii) transferring the legend drug or device to another person; or

(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of legend drugs or devices;

(2) who knowingly or intentionally:

(A) destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree or

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documentation concerning a legend drug or device in the person's possession;

(B) purchases or receives legend drugs or devices from a person not authorized to distribute legend drugs or devices in wholesale distribution;

(C) sells, barters, brokers, or transfers a legend drug or device to a person not authorized to purchase the legend drug or device in the jurisdiction in which the person receives the legend drug or device in a wholesale distribution;

(D) forges, counterfeits, or falsely creates a pedigree or documentation;

(E) falsely represents a factual matter contained in a pedigree or documentation; or

(F) fails to record material information required to be recorded in a pedigree or documentation; or

(3) who:

(A) possesses a required pedigree or documentation concerning a legend drug or device;

(B) knowingly or intentionally fails to authenticate the matters contained in the pedigree or documentation as required; and

(C) distributes or attempts to further distribute the legend drug or device;

commits a Class D felony.

SECTION 41. IC 25-26-14-27 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27. A wholesale drug distributor that fails to comply with the conditions **and requirements** described in section 17, **17.2, 17.3, 17.8, 17.9, or 20** of this chapter commits a Class D felony.

SECTION 42. IC 34-24-1-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. (a) The following may be seized:

(1) All vehicles (as defined by IC 35-41-1), if they are used or are intended for use by the person or persons in possession of them to transport or in any manner to facilitate the transportation of the following:

(A) A controlled substance for the purpose of committing, attempting to commit, or conspiring to commit any of the following:

(i) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).

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(ii) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).

(iii) Dealing in a schedule IV controlled substance (IC 35-48-4-3).

(iv) Dealing in a schedule V controlled substance (IC 35-48-4-4).

(v) Dealing in a counterfeit substance (IC 35-48-4-5).

(vi) Possession of cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-6).

(vii) Dealing in paraphernalia (IC 35-48-4-8.5).

(viii) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

(B) Any stolen (IC 35-43-4-2) or converted property (IC 35-43-4-3) if the retail or repurchase value of that property is one hundred dollars ($100) or more.

(C) Any hazardous waste in violation of IC 13-30-6-6.

(D) A bomb (as defined in IC 35-41-1-4.3) or weapon of mass destruction (as defined in IC 35-41-1-29.4) used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism (as defined by IC 35-41-1-26.5).

(2) All money, negotiable instruments, securities, weapons, communications devices, or any property used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism or commonly used as consideration for a violation of IC 35-48-4 (other than items subject to forfeiture under IC 16-42-20-5 or IC 16-6-8.5-5.1 before its repeal):

(A) furnished or intended to be furnished by any person in exchange for an act that is in violation of a criminal statute;

(B) used to facilitate any violation of a criminal statute; or

(C) traceable as proceeds of the violation of a criminal statute.

(3) Any portion of real or personal property purchased with money that is traceable as a proceed of a violation of a criminal statute.

(4) A vehicle that is used by a person to:

(A) commit, attempt to commit, or conspire to commit;

(B) facilitate the commission of; or

(C) escape from the commission of;

murder (IC 35-42-1-1), kidnapping (IC 35-42-3-2), criminal confinement (IC 35-42-3-3), rape (IC 35-42-4-1), child molesting (IC 35-42-4-3), or child exploitation (IC 35-42-4-4), or an offense

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under IC 35-47 as part of or in furtherance of an act of terrorism.

(5) Real property owned by a person who uses it to commit any of the following as a Class A felony, a Class B felony, or a Class C felony:

(A) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).

(B) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).

(C) Dealing in a schedule IV controlled substance (IC 35-48-4-3).

(D) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

(6) Equipment and recordings used by a person to commit fraud under IC 35-43-5-4(11).

(7) Recordings sold, rented, transported, or possessed by a person in violation of IC 24-4-10.

(8) Property (as defined by IC 35-41-1-23) or an enterprise (as defined by IC 35-45-6-1) that is the object of a corrupt business influence violation (IC 35-45-6-2).

(9) Unlawful telecommunications devices (as defined in IC 35-45-13-6) and plans, instructions, or publications used to commit an offense under IC 35-45-13.

(10) Any equipment used or intended for use in preparing, photographing, recording, videotaping, digitizing, printing, copying, or disseminating matter in violation of IC 35-42-4-4.

(11) Destructive devices used, possessed, transported, or sold in violation of IC 35-47.5.

(12) Cigarettes that are sold in violation of IC 24-3-5.2, cigarettes that a person attempts to sell in violation of IC 24-3-5.2, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.2.

(13) Tobacco products that are sold in violation of IC 24-3-5, tobacco products that a person attempts to sell in violation of IC 24-3-5, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.

(14) If a person is convicted of an offense specified in IC 25-26-14-26(b) or IC 35-43-10, the following real or personal property:

(A) Property used or intended to be used to commit, facilitate, or promote the commission of the offense.

(B) Property constituting, derived from, or traceable to the gross proceeds that the person obtained directly or indirectly as a result of the offense.

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(b) A vehicle used by any person as a common or contract carrier in the transaction of business as a common or contract carrier is not subject to seizure under this section, unless it can be proven by a preponderance of the evidence that the owner of the vehicle knowingly permitted the vehicle to be used to engage in conduct that subjects it to seizure under subsection (a).

(c) Equipment under subsection (a)(10) may not be seized unless it can be proven by a preponderance of the evidence that the owner of the equipment knowingly permitted the equipment to be used to engage in conduct that subjects it to seizure under subsection (a)(10).

(d) Money, negotiable instruments, securities, weapons, communications devices, or any property commonly used as consideration for a violation of IC 35-48-4 found near or on a person who is committing, attempting to commit, or conspiring to commit any of the following offenses shall be admitted into evidence in an action under this chapter as prima facie evidence that the money, negotiable instrument, security, or other thing of value is property that has been used or was to have been used to facilitate the violation of a criminal statute or is the proceeds of the violation of a criminal statute:

(1) IC 35-48-4-1 (dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine).

(2) IC 35-48-4-2 (dealing in a schedule I, II, or III controlled substance).

(3) IC 35-48-4-3 (dealing in a schedule IV controlled substance).

(4) IC 35-48-4-4 (dealing in a schedule V controlled substance) as a Class B felony.

(5) IC 35-48-4-6 (possession of cocaine, a narcotic drug, or methamphetamine) as a Class A felony, Class B felony, or Class C felony.

(6) IC 35-48-4-10 (dealing in marijuana, hash oil, or hashish) as a Class C felony.

SECTION 43. IC 35-43-10 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]:

Chapter 10. Legend Drug or Device Deception

Sec. 1. The definitions in IC 25-26-14 apply throughout this chapter.

Sec. 2. A person who knowingly or intentionally:

(1) possesses a contraband legend drug or device;

(2) sells, delivers, or possesses with intent to sell or deliver a contraband legend drug or device;

(3) forges, counterfeits, or falsely creates a label for a legend

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drug or device or falsely represents a factual matter contained on a label of a legend drug or device; or

(4) manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug or device;

commits legend drug or device deception, a Class D felony.

Sec. 3. A person:

(1) who knowingly or intentionally manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug or device; and

(2) whose act under subdivision (1) results in the death of an individual;

commits legend drug or device deception resulting in death, a Class A felony.

SECTION 44. [EFFECTIVE JULY 1, 2005] **(a) IC 25-26-14, as amended by this act, applies:**

(1) on July 1, 2005, for an initial license issued under IC 25-26-14, as amended by this act; and

(2) on the first expiration date occurring after December 31, 2005, for renewal of a license issued under IC 25-26-14, before amendment by this act.

(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs and devices. The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in Indiana. The board may establish the requirements and guidelines for the pilot program.

(c) This SECTION expires December 31, 2007.

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1745, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill do pass.

BECKER, Chair

Committee Vote: yeas 9, nays 0.

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HOUSE MOTION

Mr. Speaker: I move that House Bill 1745 be amended to read as follows:

Page 3, line 39, before "and a" delete "distributor" and insert "**distributor, including any affiliated group (as defined in Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member,**".

Page 3, line 41, delete "or".

Page 4, line 1, delete "distributors." and insert "**distributors; or**".

Page 4, between lines 1 and 2, begin a new line block indented and insert:

"**(3) has a verifiable account with the manufacturer and a minimal transaction or volume requirement limit of:**

(A) five thousand (5,000) units per company in the previous twelve (12) months; or

(B) twelve (12) purchases at the manufacturer's minimum purchasing requirement per invoice in the previous twelve (12) months.".

Page 4, line 8, delete "or".

Page 4, between lines 8 and 9, begin a new line block indented and insert:

"**(4) a drug approved by the federal Food and Drug Administration; or**".

Page 4, line 9, delete "(4)" and insert "**(5)**".

Page 7, line 35, delete "document" and insert "**statement or record**".

Page 7, line 37, after "manufacturer" insert "**or, except for drugs on the specified list of susceptible products, from the last authorized distributor of record**".

Page 8, line 5, delete "and".

Page 8, line 6, after "number;" insert "**and**".

Page 8, between lines 6 and 7, begin a new line double block indented and insert:

"**(G) proprietary and established name;**".

Page 8, line 41, delete "designated by the board," and insert "**established by the board, the board's agent,**".

Page 9, line 6, strike "distribution of" and insert "**to distribute**".

Page 9, line 9, after "sale" insert "**or transfer**".

Page 9, line 40, strike "or".

Page 10, line 1, delete "pharmacy." and insert "pharmacy;".

Page 10, between lines 1 and 2, begin a new line block indented and

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insert:

"**(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23; or**

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.".

Page 11, line 30, delete "December 31," and insert "**June 30,**".

Page 12, line 38, after "board," insert "**including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution,**".

Page 13, between lines 4 and 5, begin a new line blocked left and insert:

"**However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.**".

Page 13, line 6, after "year" insert "**after the wholesale drug distributor's license is no longer valid or sixty (60) days**".

Page 16, line 27, after "siblings." insert "**Information collected under this subdivision is confidential.**".

Page 19, line 16, delete "products." and insert "**products or that leaves the normal distribution chain of custody from the manufacturer to a wholesale drug distributor, to a pharmacy, and to the patient or the patient's agent.**".

Page 19, line 21, delete "Effective" and insert "**After**".

Page 19, line 21, after "2007," insert "**at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor,**".

Page 19, line 23, delete "for each legend drug received" and insert "**to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.**".

Page 19, delete line 24.

Page 24, line 10, delete "including," and insert "**including**".

Page 24, line 11, delete "effective January 1, 2007,".

Page 24, line 11, after "in" insert "**accordance with standards and requirements of the board under subdivision (3)(C)(iii).**".

Page 24, delete lines 12 through 14.

Page 36, between lines 31 and 32, begin a new paragraph and insert:

"**(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs and devices. The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in**

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Indiana. The board may establish the requirements and guidelines for the pilot program.".

Page 36, line 32, delete "(b)" and insert "**(c)**".

(Reference is to HB 1745 as printed January 26, 2005.)

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